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CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence is being forwarded via facsimile transmission to fax no. (571) 273-8300 to the attention of Examiner Gilligan, Mail Stop: AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313 on the date indicated below.

October 10, 2005
Date

Brenda L. Garcia

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Lewis, et al.	Confirmation No. 9722
Serial No.: 09/812,704	Examiner: Christopher Gilligan
Filed: March 19, 2001	Group Art Unit: 3626
For: ***METHODS AND SYSTEMS FOR HEALTHCARE PRACTICE MANAGEMENT***	Attorney Docket No. 044258.000003

SECOND DECLARATION OF RICHARD G. FISCELLA UNDER 37 CFR 1.132

Mail Stop AF
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Richard G. Fiscella, state the following:

1. I have a Bachelor of Science, in Pharmacy (1976) degree and a Master of Public Health (1985) degree. I am a Registered Pharmacist, having extensive experience in pharmacology and in academia. I have published over eighty research or review papers with an emphasis in ophthalmology, infectious diseases and pharmacoeconomics. I have been the principal or co-investigator on numerous animal and human studies; researcher and speaker for several major pharmaceutical companies and since 1982 have participated in over one hundred ocular pharmacology presentations. Moreover since 1981, I have held several professorships in pharmacy practice. I hold numerous memberships in professional societies one of which is the

Academy of Managed Care Pharmacy. I currently am a Clinical Professor in the Department of Pharmacy Practice for the University of Illinois.

2. I am familiar with and understand the subject matter of the above-identified patent application. I have studied the application and the amendments to the application and the cited patent documents of record in the application.

3. I have read and studied U.S. Patent No. 6,370,511 (hereinafter "Dang") attached at Exhibit A; I have read the article *New Compensation Model Improves Physician Productivity* authored by Alexandra Davis and C. Hardy Thompson and published in Healthcare Financial Management, July 1999, 53, 7, pg. 46 (hereinafter "Davis"), attached at Exhibit B, which outlines the development of a new compensation plan that bases pay on the application of a collection rate percentage to each physician's gross fee-for-service billings; and lastly, I have read and studied U.S. Patent No. 6,012,035 (hereinafter "Freeman") attached as Exhibit C. I also have read and studied the other patent documents cited in the U. S. Patent and Trademark Office in this matter as listed in the attached Exhibit D.

4. In my opinion, the present claimed invention, Claims 1-37, 39-46 and 51-56, advantageously provides a system and method for managing a healthcare practice which enhances profitability of the healthcare practice and is unique and operationally quite different than other systems and methods I have seen before and as set forth in the patent documents at Exhibits A, B and C. It is my opinion that the claimed invention, Claims 1-37, 39-46 and 51-56 would not be obvious to one of ordinary skill in the art at the time this application was filed. It is also my opinion that one skilled in the art would lack motivation to combine Dang and Davis or Dang, Davis, and Freeman to somehow arrive at the claimed invention.

5. For example, in my opinion, the present claimed invention transforms physician's cost management behavior to enhance profitability of healthcare practices and insurance networks by identifying physicians that are not profitable because of cost management behavior and provides a method and system of intervention to change the management behavior of the physician. Further, the establishment of cost norms with predetermined reimbursement amounts would not be an obvious development in view of the patent documents cited at Exhibits A, B and C, individually or in combination.

6. I believe that the present claimed invention as set forth in Claims 1-37, 39-46, and 51-56 offers a unique and viable solution for identifying, measuring, and controlling costs and cost-effectiveness of care. The present claimed invention will and does provide an important contribution to healthcare management.

7. Also, for example, as reasons for lack of motivation to combine these patent documents and for lack of obviousness of the claimed invention, for example, management can be defined in three areas: to administer, control and cope. The Freeman and Dang patents focus on "administration" (See Freeman, Col. 3, lines 1-9 and Dang, Col. 1, lines 43-54); whereas, the present claimed invention focuses on cost "control" (See present application, e.g. Claim 1, lines 9-18, Claim 8, lines 1-7, Claim 10, lines 1-9, Claim 13, lines 9-19, Claim 20, lines 1-7 and, Claim 21, lines 1 – 9). When effecting a change program, the process must address: (1) what to change, (2) what to change to, and (3) how to cause or affect the change. Freeman and Dang (See Freeman, Col. 2, lines 45-53 and Dang, Col. 1, lines 26-31) show which cooperative entity is responsible for the costs, as does the present application (See present application, e.g. Claim 15, lines 1 – 6). Dang (See Dang, Col. 10, line 67 - Col. 11, line 18) quantifies the costs and compares them to others on an adjusted basis, while the present application takes a related approach for comparison (See present application, e.g. Claim 15, lines 1 – 6). The present claimed invention, however, is critical because in cost control it shows how to cause or affect the change (See present application, e.g. Claim 13, lines 15 – 19; Claim 17, lines 1 – 7; Claim 19, lines 1 – 6; and Claim 21, lines 1 – 2). Freeman and Dang, on the other hand, do not offer a change process or solution for controlling costs (expenses), individually or in combination with Davis (See Davis, Para. 17, line 1 – 2). The present claimed invention offers a solution for measuring, controlling costs and controlling the cost effectiveness of care. Unlike Lewis, nowhere in Freeman, Dang, or Davis are standards of care identified (See present application, e.g. Claim 17, line 1 – 7), quantified (See present application, e.g. Claim 14, line 1 – 6), and used as a measurement standard for physician performance (See present application, e.g. Claim 15, line 1 – 6). As such, it is difficult to understand how one skilled in the art would have motivation to combine the patents, and it is my understanding that the result still would not be the present claimed invention as set forth in Claims 1-37, 39-46 and 51-56.

8. Further, for example, as additional reasons, the Davis article (See Davis, Para. 17, line 1 – 2) describes revenue; the present claimed invention describes expenses (See present application, e.g. Claim 24, line 1 – 6). Davis (See Davis, Para. 21, line 1 – Para. 22, line 11) requires physicians to increase their gross billings to maximize their compensation. Conversely, Lewis (See present application, e.g. Claim 13, line 1 – 5 and Claim 17, line 1 – 7) compels physicians to follow researched standards of care to only incur necessary ancillary medical costs as a means to increase practice or insurer profitability. Lewis supports this action with several methods of physician behavior modification (See present application, e.g. Claim 13, line 15 – 19; Claim 17, line 1 – 7; Claim 19, line 1 – 6; and Claim 21, line 1 – 2). However, Davis' (See Davis, Para. 23, line 4 – 7) behavior modification is only to induce physicians to increase billing revenues through marketing to increase the number of patients, which is rewarded under a full revenue recognition capitation model (See Davis, Para. 20, line 7 – 9), as well as to increase the prescription of ancillary testing services to maximize billings per patient. Davis does not focus on measuring or controlling costs. Rather, Davis (See Davis, Para. 4, line 4 – Para. 5, line 12) deals strictly with physicians on the payroll of a specific healthcare organization and offers a change process or measurement system which does not address clinically appropriate steps to increase their measures. Increased productivity does not necessarily increase the quality of care or control costs (See Davis, Para. 17, line 1 – 2); however, it most assuredly will increase the workload of the physician. The present claimed invention employs physician behavior modification, for example, in the areas of increased utilization of step therapies, greater training in clinical prescribing guidelines, and tools to counsel patients on the perils of starting new treatment with last-line, high cost drugs, all of which are cost control measures (See present application, e.g. Claim 17, line 1 – 7).

9. Additionally, as described in the background section of the present patent application, as well-known in our society, as discussed abundantly in literature, as observed by me, and based on my experience, there has been a long felt need for a solution to the problem identified and addressed so elegantly by the inventors in the present application, especially in terms of identifying, measuring and controlling costs and controlling the cost effectiveness of care. Notably, as described in paragraphs 6-8 above, none of these patent documents recognize or address a change process or solution for controlling costs, and thus further confirms and

indicates to me that this long felt need was not being met prior to Applicant's present application, including Claims 1-37, 39-46, and 51-56.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Sec. 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the publication or any patent issued thereon.

FURTHER DECLARANT SAYETH NOT.

9/21/05
Date

By: Richard G. Fiscella

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